

REMARKS / ARGUMENTS

This amendment is submitted in full response to the outstanding Office Action dated March 24, 2008 wherein claims 1-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morita (U.S. Patent No. 5,628,765) in view of Czernecki et al. (U.S. Patent No. 5,356,420).

For the reasons set forth in greater detail hereinafter, the above noted, outstanding rejections are respectively traversed.

Applicant's Invention

Applicant's invention is directed to a lancet device used for piercing the skin of an individual for various medical purposes as outlined in detail in the specification, drawings, and claims, as originally filed. As such, the lancet device includes a housing having an at least partially open interior and a lancet movably disposed within the interior and including a piercing tip which, when fired extends out of the housing into piercing engagement with a correspondingly disposed portion of the individual's body. In addition, the lancet device includes a biasing assembly disposed within the housing. A cocking seat is movable within the housing with and relative to the lancet

and is structured to position the lancet and the piercing tip in a cocked orientation specifically relative to the biasing assembly.

An engagement assembly is disposed on and movable with said lancet and said cocking seat, wherein said engagement assembly releasably connects said lancet and said cocking seat. In at least one preferred embodiment, a release element is positioned and cooperatively structured to disengage the cocking seat from the lancet, when the cocking seat has positioned the engagement assembly into interruptive engagement with the release element. Accordingly the biasing assembly is disposed into direct biasing engagement with the lancet upon disengagement between the lancet and said cocking seat thereby accomplishing a firing of the piercing tip such that it is disposed exteriorly of the housing into piercing engagement with an individual.

In more specific terms and as now defined in the claims present in this application, the engagement assembly includes an engagement member mounted on said lancet and releasably engaging said cocking seat. The engagement member is disposed, by movement of the cocking seat, into interruptive relation with said release element causing a release of said lancet from said cocking seat.

In at least some of the preferred embodiments of Applicant's claimed invention, a single use pivot movably interconnects the engagement member of the engagement assembly and a remainder of said lancet. As such, the single use pivot is structured to be at least deformed upon releasing engagement of said release element with said engagement assembly. Further, the single use pivot is more specifically defined as a breakable hinge disposed in interconnecting relation between said engagement member and a remainder of said lancet. As such, reuse of the engagement member and the lancet is prevented due to the single use pivot being a breakable hinge, which serves to releasably interconnect engagement member to a remainder of the lancet.

In certain additional embodiments, the engagement assembly is further comprises a retention member or lip, releasably engaging the engagement member and at least partially movable with and relative to said lancet as said cocking seat serves to position the lancet into a cocked orientation specifically relative to the biasing assembly.

References of Record

In support of the outstanding rejection under 35 U.S.C.

103(a), the Examiner contends that Morita discloses a lancet device including a housing 16, a cocking seat 34, a lancet 46 and a biasing assembly 54. Further, the Examiner contends that Morita also discloses an engagement element 48A that engages the cocking seat 34 "---to hold against the force of the biasing assembly" as represented in Figure 13. The Examiner further contends that a release element 68 engages and pivots the engagement element to release it from the cocking seat 34 to allow the force of the biasing assembly to fire the lancet.

A thorough review of the Morita reference and the Examiner's contentions as to the similarity in the structure thereof with Applicant's claimed invention indicates significant differences. More specifically in the operation of the lancet assembly 10 as represented in Figure 2 of Morita, the members 14 and 16 are in the represented position. Accordingly, as the actuator 56 is depressed, the "cocking seat" 34 of the holder 16 contacts extensions or engagement members 48A on the cantilevered arms 48 attached to the lancet member 40. As such, the arms 48 and engagement members 48A **cannot be further advanced or proceed** and the lancet member is held in this initial position. As a result of the lancet member being stationary, the protrusions or "cocking seat" 34 compress and

energize the spring 54.

Therefore it is abundantly clear that the lancet 40 of the Morita is maintained in a stationary position in contrast to Applicant's claimed invention. More specifically as set forth above, newly submitted independent claim 9 as well as additional new claims dependent thereon call for a lancet being movably disposed within the open interior of the housing as well as the piercing tip connected thereto. Also, the cocking seat of Applicant's invention is movable with the lancet and is also movable relative to the lancet in order to dispose the lancet into an orientation to be fired relative to the biasing means. Thereafter, the cocking seat of Applicant's invention is released from its engagement with the lancet during the firing procedure. In order to accomplish this, an engagement assembly including an engagement member 45 is disposed on and movable with the lancet and said cocking seat, wherein said engagement assembly defines a releasable engagement between the lancet 40 and the cocking seat 30. Continued movement of the lancet by the cocking seat results in the continued movement of the engagement member 45 of the engagement assembly until it interacts with a release element 56, disposable into releasing engagement with the engagement assembly. More specifically as

the lancet 40 and engagement member 45 continue to move within the housing through pressure exerted thereon by the cocking seat 30, the engagement member 45 and the retention lip or member 34, both defining the engagement assembly, become disengaged through interruptive relation with the release element 56 of Applicant's newly claimed invention. The Applicant further wishes to emphasize that the engagement member 45 moves with and relative to the lancet 40 wherein the reception lip or member 34 moves with the cocking seat 30 and the lancet when the cocking seat is in releasable engagement with the lancet.

Therefore, Applicant respectfully contends that Morita is absent specific structural features as outlined in detail above and as now specifically recited in newly submitted claims 9-13 as well as the dependent claims remaining in this application.

In further support of the outstanding rejection 103(a), the Examiner acknowledges that Morita does not disclose the engagement element being a single use device that breaks away or deforms from the cocking seat. Applicant agrees that Morita does not disclose these features and importantly does not even suggest the need, requirement or desire of any type breakaway engagement member disposed and structured to release the lancet into a fired position while preventing reuse of the lancet and

piercing tip.

In view of the recognized deficiencies of the Morita reference, the Examiner relies on Czernecki reference which teaches the use of breakable engagement elements 11. However, it is apparent that the elements 11 of the Czernecki reference define retaining members or "wings" and most importantly are not capable of functioning as a single use pivot capable of being deformed and/or a breakable hinge as now recited in newly submitted dependent claims 11 and 12.

With primary reference to Applicant's claimed embodiments as represented in Figures 3 and 6, newly submitted dependent claim 11 calls for a single use pivot 46 **movably interconnecting the engagement member 45 to a remainder of the lancet 40**, wherein the single use pivot 45 is structured to be deformed upon releasing engagement of the release element 56 with said engagement assembly. Further, newly submitted dependent claim 12 further defines the single use pivot 46 as a breakable hinge disposed in interconnecting relation between the engagement member 45 and a remainder of the lancet 40.

A detailed review of the Czernecki reference indicates that the breakable structure referred to and relied on by the Examiner includes wings 11 secured to a piston 5 which rests

against a projection 12 of the sleeve 1. The sole purpose of the wings 11 are to keep the piston 5 and the puncturing tip 7 in a first stable position such that it is prevented from being fired until sufficient force has been exerted thereon by the biasing or power spring 9. Accordingly, the function and the structure of the retaining wings 11 differs in purpose and operability from Applicant's single use pivot 46 which may be more specifically defined as a breakable hinge. As stated above, the single use pivot 46 serves to interconnect the engagement member to the remainder of the lancet. No such structure or function exists in the disclosure of Czernecki.

As such, Applicant respectfully contends that the combining of the generally "breakable" structure 11 of Czernecki with the Morita reference is an application of the forbidden practice of "hindsight" knowledge of Applicant's invention. This is especially true based on the fact that Morita does not require, suggest or even provide for any type of breakable portion and more specifically does not provide or suggest a teaching of a single use pivot which may be in the form of a deformable pivot or breakable hinge.

Based on the above, Applicant respectfully contends that Applicant's claimed invention is clearly distinguishable over

the Morita and Czernecki references whether considered singularly or in combination with one another.

Conclusion

Based on the above amendments and remarks reconsideration of this application is hereby requested. It is believed that this application is now in condition for allowance and such action is respectfully requested.

In the event that any fee may be required by the filing of this paper, the Commissioner is hereby authorized to charge any fees and/or credit to our **Deposit Account No. 13-1227**.

Respectfully Submitted,

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